NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICALS USA, INC., through its GATE PHARMACEUTICALS division, Plaintiff, v. EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC., Defendants.	Hon. Garrett E. Brown, Jr. Civil Action No. 08-2344 (GEB) **MEMORANDUM OPINION**

BROWN, Chief Judge:

This matter comes before the Court on the renewed motion to dismiss for lack of subject matter jurisdiction (Doc. No. 20) filed by Defendants Eisai Co., Ltd. and Eisai Medical Research, Inc. ("Eisai"). In its Amended Complaint, Plaintiff Teva Pharmaceuticals USA ("Teva") through its Gate Pharmaceuticals ("Gate") division, seeks a declaratory judgment of noninfringement of four patents: U.S. Patent Nos. 5,985,864 ("the '864 patent"); 6,140,321 ("the '321 patent"); 6,245,911 ("the '911 patent"); and 6,372,760 ("the '760 patent"). This Court will refer to these four patents collectively as the "DJ patents." In its motion to dismiss, Eisai contends that this Court lacks subject matter jurisdiction because Teva's claims for declaratory judgment present no justiciable controversy. For the following reasons, Eisai's motion will be granted.

Background

Resolution of Eisai's motion requires understanding of the complicated statutory scheme for the approval of new and generic drugs under the Hatch-Waxman Act.[1] As the Federal Circuit has often stated, the Hatch-Waxman Act aims to "balance two competing interests in the pharmaceutical industry: '(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (quoting *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

I. The Hatch-Waxman Act

The Hatch-Waxman Act requires that before a drug manufacturer can market a new drug, it must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") for approval. 21 U.S.C. § 355(a). In addition to extensive testing and safety information concerning the drug, the manufacturer must also submit the patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1). Once the NDA is approved, the FDA lists this patent information with the approved drug in its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book." *See* 21 U.S.C. §§ 355(b)(1), 355(j)(A)(ii)(iii).

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[1]The Hatch-Waxman Act is the title commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

Generic drug manufacturers may obtain FDA approval for generic versions of previously-approved drugs by filing an Abbreviated New Drug Application ("ANDA"), without having to repeat the extensive testing required for a new drug application. *See* 21 U.S.C. § 355(j). When submitting an ANDA to the FDA, the Hatch-Waxman Act requires a generic manufacturer to make one of the following four certifications with respect to each of the patents listed in the Orange Book for the drug for which the applicant seeks approval: (1) that no patent information has been filed (a "Paragraph I" certification), (2) that the patent has expired (a "Paragraph II" certification), (3) that the patent will expire on a specific date (a "Paragraph III" certification), or (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted" (a "Paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). A company seeking to market a generic version of a listed drug prior to the expiration of the Orange Book-listed patents must file a Paragraph IV certification. The filing of a Paragraph III certification with respected to a listed patent, on the other hand, signifies that the FDA may wait until expiration of the named patent to approve the ANDA.

"In order to bring about early resolution of patent disputes between generics and pioneering drug companies, the [Hatch-Waxman] Act provides that the filing of a Paragraph IV Certification is an act of patent infringement." *Janssen*, 540 F.3d at 1356 (citing 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). Upon receiving notice from the ANDA filer of the Paragraph IV certification and its factual and legal bases, the NDA holder may bring an infringement suit on all, some, or none of the patents included in the certification. *Id.* If the NDA holder fails to bring suit on any of the patents subject to the Paragraph IV certification within 45 days of notice, the FDA may approve the ANDA. If the

NDA holder files suit, FDA approval of the ANDA is subject to a 30-month stay.

More importantly for the instant matter, the Hatch-Waxman Act provides that the first ANDA applicant to file a Paragraph IV certification with respect to a listed patent shall enjoy a 180-day period of generic marketing exclusivity. This exclusivity period serves "to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008). The FDA may not approve a subsequent Paragraph IV ANDA until the expiration of the first-filer's exclusivity period. The first-filer may take advantage of the 180-day exclusivity period regardless of whether it actually establishes that the listed patents subject to the Paragraph IV certification are invalid or not infringed by the ANDA drug. *Janssen*, 540 F.3d at 1356.

"The start of the 180-day exclusivity period is triggered by the earlier of two events: (1) the first Paragraph IV ANDA filer's commercial marketing of a drug product; or (2) a court decision of noninfringement or invalidity." *Id.* at 1357 (citing 21 U.S.C. § 355(j)(5)(B)(iv)).[2] While only the first-filer may trigger its own exclusivity period by "hitting the market," subsequent-filers can trigger the first-filer's exclusivity period via a successful court judgment. *Id.*

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[2]In December 2003, Congress amended the portion of the Hatch-Waxman Act regarding the triggering of the exclusivity period with new provisions establishing conditions under which the exclusivity period may be forfeited for various reasons. These new provisions, however, contain a grandfather clause "specifying that the amendments do not apply to Paragraph IV ANDAs filed before the date of enactment of the [amendments] or to subsequent Paragraph IV ANDAs filed after the enactment of the [amendments] if the first Paragraph IV ANDA was filed prior to enactment of the [amendments]." *Janssen*, 540 F.3d at 1357 n.2. Here, as discussed shortly, Ranbaxy Laboratories Ltd. filed the first ANDA for generic donepezil in August 2003, before the effective date of the relevant amendments. Therefore, these amendments do not apply to this case.

Congress amended the Hatch-Waxman Act in 2003 to allow for an action pursuant to 28 U.S.C. § 2201 seeking a declaratory judgment that a listed drug is invalid or not infringed by the drug for which an ANDA filer requests approval. Under the current statutory scheme, a Paragraph IV ANDA filer (whether a first-filer or a subsequent-filer) may "bring a declaratory judgment action for noninfringement or invalidity of the relevant listed patents against the patentee and NDA holder, if the patentee has not brought an infringement action within the 45-day notice period." *Janssen*, 540 F.3d at 1357 (citing 21 U.S.C. § 355(j)(5)(C)). Notably, "Congress extended federal court jurisdiction over these declaratory judgment actions 'to the extent consistent with the Constitution.'" *Id.* (quoting 35 U.S.C. § 271(e)(5)). Thus, a federal court's jurisdiction over such a declaratory judgment action depends upon whether the action presents an Article III case or controversy. *Id.* (citing *Caraco*, 527 F.3d at 1285).

II. Factual Background and Procedural History

In this matter, Eisai filed an NDA for donepezil hyrdochloride ("donepezil") for the treatment of Alzheimer's disease, and the FDA approved the NDA in 1996. Eisai markets its versions of donepezil as the prescription drug product Aricept®. Eisai listed five patents in the Orange Book for Aricept®: the four DJ patents at issue in this case, and U.S. Patent No. 4,895,841 ("the '841 patent").

In August 2003, Ranbaxy Laboratories Ltd. ("Ranbaxy") filed the first ANDA for generic donepezil. In its ANDA, Ranbaxy included a Paragraph III certification against the '841 patent, indicating its agreement to not market a generic version of Aricept® until that patent expires in November 2010. Against the four other listed patents – the DJ patents – the Ranbaxy ANDA

made Paragraph IV certifications. Despite the filing of these Paragraph IV certifications, Eisai elected not to bring an infringement action against Ranbaxy. Thus, although Eisai did not trigger any 30-month stay on FDA approval of Ranbaxy's ANDA, the Paragraph III certification forestalls FDA approval of the ANDA until after November 2010. Still, Ranbaxy's first-filer status as to its Paragraph IV certifications against the DJ patents made it eligible for the 180-day marketing exclusivity period upon FDA approval of its ANDA.

Plaintiff Teva filed its first donepezil ANDA in October 2004 ("first ANDA"). Teva's initial ANDA, like Ranbaxy's, included a Paragraph III certification against the '841 patent and Paragraph IV certifications as to the DJ patents. One year after filing this ANDA, in October 2005, Teva amended its ANDA to include a Paragraph IV certification claiming that the '841 patent is invalid for obviousness. Teva's Paragraph IV certification against the '841 patent in its amended ANDA allowed Teva to share in the 180-day exclusivity period with Ranbaxy, as both Teva and Ranbaxy were first-filers with regard to Orange Book patents for Aricept®. Upon receiving notice of the Paragraph IV certification against the '841 patent, Eisai filed a patent infringement suit against Teva in this Court claiming infringement of the '841 patent. *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 05-5727 (D.N.J.). By timely suing for infringement, Eisai secured a 30-month stay of FDA approval of Teva's first ANDA. Eisai did not file suit on the DJ patents.

In 2005, Teva filed a new, separate ANDA in the name of Gate Pharmaceuticals ("second ANDA" or "Gate ANDA"). Teva's Amended Complaint in this matter identifies Gate merely as a division of Teva. (Am. Compl. ¶ 1.) Both Teva and Gate share the same principal place of business, and there is no evidence that Gate is incorporated or otherwise exists separately from

its status as a division of Teva.[3] This second Teva ANDA specified a different form of generic donepezil – employing a different active pharmaceutical ingredient – than stated in Teva's first ANDA. According to Teva, the FDA required a separate ANDA because the form of donepezil encompassed in the second ANDA differs from that described in the first ANDA, and the FDA also "requested that [the second ANDA] be filed in a different name to avoid confusion between the two products." (Teva Br. at 5.) The initial second ANDA included Paragraph III certifications against all five listed patents for Aricept®.

Nearly two years after filing the second ANDA, Gate amended the second ANDA to include Paragraph IV certifications against all five listed Aricept® patents. Upon notice of the amendment, in November 2007, Eisai sued Teva and Gate for infringement of the '841 patent. *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 07-5489 (D.N.J.). Until that time, the only issue litigated in the first infringement action, regarding the first Teva ANDA, was Teva's affirmative defense of obviousness with regard to the '841 patent. In April 2007, Teva stipulated that its generic drug would constitute infringement of various claims of the '841 patent, unless Teva proves in the *Eisai v. Teva* litigation that the '841 patent is invalid or unenforceable. (No. 05-5727, Doc. No. 65.) In late 2007, Teva amended its answers in both '841 patent infringement actions to add the affirmative defense of inequitable conduct and withdraw the obviousness

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[3]Courts have recognized that Gate is merely an unincorporated division of Teva. *See, e.g., Eli Lilly & Co. v. Sicor Pharms., Inc.*, No. 06-238, 2007 WL 1245882, at *3 (S.D. Ind. Apr. 27, 2007) ("In addition to generic drug sales, Teva USA sells drugs through its branded division, Gate Pharmaceuticals."); *In re Diet Drugs Prods. Liab. Litig.*, 990 F. Supp. 834, (J.P.M.L. 1998) (naming "Teva Pharmaceuticals, USA, Inc., and its sales division Gate Pharmaceuticals"). Indeed, the website for Gate Pharmaceuticals states that "Gate Pharmaceuticals was created in 1990 to market innovative pharmaceutical products in the United States. Gate Pharmaceuticals is a division of Teva Pharmaceuticals USA, a subsidiary of Teva Pharmaceutical Industries, Ltd., Israel's leading pharmaceutical company." *See* http://www.gatepharma.com/.

defense. The two '841 patent infringement actions were subsequently consolidated in early 2008. (No, 05-5727, Doc. No. 113.)

The 30-month stay of approval of Teva's first ANDA triggered by Eisai's timely infringement suit on the '841 patent expired in April 2008. The FDA approved Teva's first ANDA on April 28, 2008. Teva had previously notified Eisai that it intended to launch a generic version of Aricept® immediately upon receiving final approval of its first ANDA. Prior to the FDA's approval of the first ANDA, Eisai filed a motion for a preliminary injunction to prevent Teva from marketing any form of generic donepezil. In the briefing on Eisai's preliminary injunction motion, Teva made no reference to any additional restraints on its ability to market generic donepezil, such as the four other listed patents. The Honorable Harold A. Ackerman, Senior United States District Judge, granted Eisai's motion for a preliminary injunction in March 2008.[4] The preliminary injunction entered by Judge Ackerman restrained and enjoined Teva and Gate from marketing *any* drug product containing donepezil hyrdochloride as claimed in the '841 patent. *Eisai Co. v. Teva Pharms. USA, Inc.*, Nos. 05-5727/07-5489, 2008 WL 1722098, at *13 (D.N.J. Mar. 28, 2008) (specifically naming Teva and Gate as subject to the injunction). This preliminary injunction remains in effect, as the '841 patent litigation remains pending. Therefore, Teva and Gate are presently precluded from marketing any form of generic donepezil until at least November 2010, at the expiration of the '841 patent, and this bar to market entry will remain in effect unless Teva ultimately prevails in the '841 patent case.

In May 2008, Teva filed the instant declaratory judgment action regarding the four DJ

[4]The '841 patent infringement actions, along with the instant matter, were initially assigned to Judge Ackerman. Judge Ackerman presided over these cases for several years. In August 2009, all of these cases were reassigned to the undersigned.

patents. As Teva's initial Complaint acknowledged, Eisai had previously filed statutory disclaimers, pursuant to 35 U.S.C. § 253, with the U.S. Patent and Trademark Office regarding two of the DJ patents, the '321 and '864 patents. (Compl. ¶ 10; Gill Decl., Ex. 1.) Eisai's formal disclaimers of these patents, in 2006 and 2007 respectively, "ha[ve] the effect of canceling the claims from the patent[s] and the patent[s] [are] viewed as though the disclaimed claims had never existed in the patent[s]." *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). Therefore, based on the disclaimers, Eisai "has no further right to enforce the claims that have been disclaimed, or to obtain a reissue of any of these claims." *Merck & Co. v. Apotex, Inc.*, No. 06-5789, 2007 WL 4082616, at *5 (D.N.J. Nov. 15, 2007). Despite the Paragraph IV certifications filed against the two other DJ patents, the '911 and '760 patents, Eisai has never brought suit against Teva or any other ANDA filer to enforce these patents.

In its initial complaint in this matter, Teva sought a declaratory judgment of noninfringement of all four DJ patents with respect to the second ANDA filed in Gate's name (Counts I-IV), and of noninfringement with respect to the two non-disclaimed DJ patents, the '911 and '760 patents, with respect to Teva's first ANDA (Counts V-VI). Regarding Teva's first ANDA, the initial complaint alleged that because Eisai did not file suit on the non-disclaimed DJ patents, but they remain listed in the Orange Book, Teva faced a restraint on its ability to commercially market generic donepezil because of the potential risk of future suit on those patents by Eisai. With regard to the second ANDA filed in Gate's name, however, Teva asserted two distinct injuries justifying declaratory judgment jurisdiction: 1) restraint on its ability to market generic donepezil based on potential risk of future suit; and 2) that without a judgment of non-infringement on all four DJ patents, Gate would be unable to win FDA approval of its

ANDA ("FDA-approval-blocking injury"). This latter argument amounts to the theory that without a court decision on the four DJ patents, Ranbaxy's exclusivity period with regard to those patents will not be triggered, thus forestalling FDA approval of the Gate ANDA.

After being served with the complaint, Eisai informed Teva that it had disclaimed the '864 and '321 patents, and offered to enter into a binding covenant-not-to-sue on any of Teva's ANDA products based on the '911 and '760 patents. Eisai subsequently filed a motion to dismiss for lack of subject matter jurisdiction. After Eisai filed its motion, the parties negotiated a covenant-not-to-sue on the '911 and '760 patents. In the covenant-not-to-sue, Eisai unconditionally agreed that it would not assert the '911 and '760 patents against Teva or its successors with respect to any generic donepezil formulation described in both Teva ANDAs. (Michael Decl., Ex. 34.) Teva subsequently dismissed Counts V and VI of the initial complaint, as those claims concerned the first Teva ANDA and the potential risk of suit on the patents now subject to the covenant-not-to-sue.

However, instead of responding to the remainder of Eisai's motion to dismiss, Teva filed an Amended Complaint. The Amended Complaint deleted all meaningful reference to Teva itself and Teva's first ANDA, omitted any allegation of commercial restraint based on risk of future suit, and only raised allegations made by Gate as a division of Teva with regard to the second ANDA. In the Amended Complaint, Teva clearly alleges FDA-approval-blocking injury as the sole basis for declaratory judgment jurisdiction, thereby requesting a judgment of non-infringement as to all four DJ patents. Teva's Amended Complaint states that

> [e]ven though Eisai Co. Ltd has disclaimed the '864 and '321 patents and has provided GATE with a covenant not to sue with respect to the '911 and '760 patents, they remain in the FDA Orange Book. As a

> result, GATE is suffering actual injury because it will not be able to obtain final FDA approval of its ANDA as a result of 21 U.S.C. § 355(j)(5)(B)(4). A court decision finding the patents not infringed is the only way to redress this injury.

(Am. Compl. ¶ 14.) Shortly after Teva filed its Amended Complaint, Eisai filed the instant renewed motion to dismiss.

Analysis

I. Standard of Review

A. Rule 12(b)(1)

Eisai has renewed its motion to dismiss Teva's Amended Complaint for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). Because Eisai presents a factual challenge to this Court's subject matter jurisdiction by challenging Teva's jurisdictional allegations, this Court "may consider and weigh evidence outside the pleadings to determine if it has jurisdiction." *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000); *see also Eisai Co. v. Mutual Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *14 (D.N.J. Dec. 20, 2007). In resolving a factual attack to jurisdiction, "no presumptive truthfulness attaches to the nonmovant's allegations, and the existence of disputed material facts will not preclude the Court from evaluating the merits of jurisdictional claims." *Merck*, 2007 WL 4082616, at *4 (citing *Robinson v. Dalton*, 107 F.3d 1018, 1021 (3d Cir. 1997)). As the nonmovant, Teva bears the burden of persuasion as to the existence of subject matter jurisdiction. *See, e.g.*, *Merck*, 2007 WL 4082616, at *3.

B. Declaratory Judgment Jurisdictional Standard

Congress has extended declaratory judgment jurisdiction under the Declaratory Judgment Act to Paragraph IV ANDA filers seeking to establish noninfringement or invalidity of listed patents "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The Declaratory Judgment Act provides that "[i]n a case of *actual controversy* within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added).

No bright-line rule governs whether a case presents an actual controversy. *See PharmaNet, Inc. v. DataSci Ltd. Liab. Co.*, No. 08-2965, 2009 WL 396180, at *4 (D.N.J. Feb. 17, 2009). The Supreme Court has required only that the dispute be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). Because the Hatch-Waxman Act authorizes declaratory judgment actions to the full extent consistent with the Constitution, this Court must apply the all-the-circumstances test for declaratory judgment jurisdiction "guided by the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy. In particular, an action is justiciable under Article III only where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage of the litigation." *Caraco*, 527 F.3d at 1291 (internal citations omitted).

"Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

MedImmune reiterated this "all-the-circumstances" standard and rejected the exclusive "reasonable apprehension of suit" test previously applied by the Federal Circuit. *See, e.g., Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007). "Following *MedImmune*, proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy." *Caraco*, 527 F.3d at 1291; *see also PharmaNet*, 2009 WL 396180, at *4 (observing that all-the-circumstances test did not make reasonable apprehension of suit irrelevant). The declaratory judgment plaintiff bears the burden of proof to show jurisdiction at the time of filing and throughout the case. *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007). Even if this Court finds the constitutional prerequisites to jurisdiction to be satisfied, it retains the discretion pursuant to the Declaratory Judgment Act to decline declaratory judgment jurisdiction. *See, e.g., Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995) ("[D]istrict courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites.").

II. Teva's Alleged FDA-Approval-Blocking Injury

Because Eisai has disclaimed two of the DJ patents, and has entered into a binding

covenant not to sue Teva on the other two DJ patents, Eisai has no right to enforce the DJ patents. Teva faces no restraint on its ability to market generic donepezil based on the potential that Eisai may bring suit to prevent such marketing based on the DJ patents. Teva amended its complaint in this matter to remove any allegation of such injury based on reasonable apprehension of suit. Therefore, on first blush, there would appear to be an absence of "adverse legal interests" between Teva and Eisai "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Indeed, if "a threat of suit was the only action allegedly taken by [Eisai] that effectively excluded [Teva] from the marketplace, the covenant not to sue would moot [Teva's] case and divest [this Court] of Article III jurisdiction." *Caraco*, 527 F.3d at 1296.

However, Teva asserts a different form of injury at the hands of Eisai: FDA-approval-blocking injury. Based on Teva's first ANDA, Teva shares a 180-day exclusivity period on the marketing of generic donepezil with Ranbaxy. Ranbaxy's exclusivity period results from its first-filed Paragraph IV certifications against the DJ patents, while Teva shares in that period based on its first-filed, if belated, Paragraph IV certification against the '841 patent. The exclusivity period may be triggered either by the commercial marketing of the generic drug product by the exclusivity holder, or by a court judgment – secured by the first-filer or subsequent filers – of noninfringement or invalidity of the patent against which a Paragraph IV certification was filed. *Caraco*, 540 F.3d at 1357 (citing 21 U.S.C. § 355(j)(5)(B)(iv)). Only after the 180-day exclusivity period expires may the FDA approve a subsequently-filed ANDA, and only with such FDA approval may that ANDA filer market its generic drug.

At the present time, neither Ranbaxy nor Teva may trigger their shared 180-day

exclusivity period prior to the expiration of the '841 patent in November 2010. Ranbaxy filed a Paragraph III certification against the '841 patent, thereby forestalling FDA approval of its ANDA until the expiration of that patent. While the FDA approved Teva's first ANDA in April 2008, Judge Ackerman shortly thereafter issued a preliminary injunction precluding Teva from marketing any form of generic donepezil as claimed by the '841 patent. That injunction remains in effect as the parties litigate Eisai's '841 patent infringement suit.

For these reasons, only a court judgment of noninfringement or invalidity of the DJ patents could trigger Ranbaxy's exclusivity period at this time, and only a similar judgment as to the '841 patent could trigger Teva's exclusivity period. Absent a court judgment, the exclusivity period will not commence, at least prior to the expiration of the '841 patent, and concomitantly, the FDA will not approve any subsequent ANDAs, thereby preventing subsequent ANDA filers from marketing generic versions of donepezil. Teva, through its unincorporated Gate division, is also a subsequent ANDA filer for donepezil. Teva seeks a declaratory judgment of noninfringement as to the DJ patents so that Ranbaxy's exclusivity period may be triggered, thus lifting the barrier to FDA approval of the Gate ANDA and thereby allowing Teva to market the Gate ANDA version of generic donepezil.

Teva alleges that because Eisai listed the DJ patents in the Orange Book and failed to bring suit on them when challenged by Paragraph IV certifications, the patents' continued presence in the Orange Book without the ability for a court judgment prevents the FDA from approving the Gate ANDA under the Hatch-Waxman Act. In other words, Teva argues that Eisai is injuring Teva by effectively excluding Teva from the market. According to Teva, Eisai's infliction of this FDA-approval-blocking injury has sufficient immediacy and reality to justify

declaratory judgment jurisdiction.

III. *Caraco* and *Janssen*

In *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, the Federal Circuit recognized that FDA-approval-blocking injury could establish declaratory judgment jurisdiction for a suit brought by a subsequent Paragraph IV ANDA filer for a judgment of noninfringement with respect to patents for which the patent holder has entered into a covenant-not-to-sue. Applying the "all-the-circumstances" standard reaffirmed in *MedImmune*, the Federal Circuit held that "[i]n claiming that it has been denied the right to sell non-infringing generic drugs, [the generic manufacturer] has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy." *Caraco*, 527 F.3d at 1293-94. Teva vigorously contends that *Caraco* controls here, and declaratory judgment jurisdiction exists, because Teva stands in the same position as the plaintiff in *Caraco*.

To determine whether *Caraco* dictates the result here, this Court must consider the specific factual circumstances at issue in *Caraco*. A court in the District of Delaware recently summarized the facts of *Caraco* as follows:

> In *Caraco*, . . . the patent holder, Forest Laboratories, Inc. ("Forest"), listed multiple patents in the Orange Book in relation to its NDA. Specifically, there were two Orange Book patents: the '712 patent, which expires in 2012, and the '941 patent, which expires in 2023. Also, . . . there were two Paragraph IV ANDA filers: Ivax Pharmaceuticals, Inc. ("Ivax") filed the first ANDA, and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed the second ANDA. Both Ivax's ANDA and Caraco's ANDA pertained to the two listed patents. However, after Ivax filed its ANDA, Forest chose to sue only on the '712 patent, which was ultimately found valid, infringed, and enforceable. Later, after Caraco filed its ANDA,

> Forest sued Caraco on only the '712 patent, granting Caraco a covenant-not-to-sue on the '941 patent. In these circumstances, even if Caraco were to have achieved victory on the '712 patent, it would have been unable to go to market until Ivax completed its 180-day exclusivity period on the '941 patent, which could be no earlier than 181 days after the expiration of the '712 patent. Hoping to trigger Ivax's 180-day exclusivity on the '941 patent, and hence put itself in a position to enter the market earlier, Caraco brought a declaratory judgment action for non-infringement of the '941 patent.

Dey, L.P. v. Sepracor, Inc., 595 F. Supp. 2d 355, 359-60 (D. Del. 2009) (internal citations to *Caraco* omitted).

On these facts, the Federal Circuit concluded that Caraco had standing because Forest's listing of the DJ patents in the Orange Book "effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that [the listed patents] are invalid or not infringed by its generic drug." *Caraco*, 527 F.3d at 1292-93; *see also id.* at 1292 ("[W]here the first Paragraph IV ANDA filer has failed to trigger its own 180-day exclusivity period, the NDA holder's listing of Orange-Book patents delays a subsequent Paragraph IV ANDA filer from entering the marketplace indefinitely."). A favorable declaratory judgment "would clear the path to FDA approval that Forest's actions would otherwise deny Caraco – namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) to activate Ivax's exclusivity period." *Id.* at 1293. The Federal Circuit further held that Caraco's action was ripe because the issues were fit for judicial decision and because withholding judicial consideration would have an immediate and substantial impact on Caraco by creating a potential for lost profits. *Id.* at 1295-96. Finally, the Federal Circuit found that Forest's covenant-not-to-sue did not render Caraco's declaratory judgment claim moot because Caraco demonstrated that the Orange Book-listing of the patent on which Forest agreed not to sue effectively prevented Caraco

from entering the drug market in "a manner that is unique to the Hatch-Waxman context." *Id.* at 1296. As the Federal Circuit stated, under the Hatch-Waxman Act "an NDA holder's covenant not to sue a subsequent Paragraph IV ANDA filer does not affect the FDA's authority to approve the ANDA." *Id.* at 1296.

The Federal Circuit later declined to apply *Caraco* under factual circumstances where the first Paragraph IV filer and the subsequent filer, but for the first-filer's exclusivity period, faced the same limitations on entering the market. In *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, the NDA holder listed three patents in the Orange Book. The first ANDA filer, which coincidentally happened to be Teva, filed Paragraph IV certifications as to two of the patents and a Paragraph III certification as to the third. Apotex, Inc. ("Apotex"), a subsequent ANDA filer who had filed Paragraph IV certifications against all three patents, sought a declaratory judgment of noninfringement regarding the two patents against which Teva filed its Paragraph IV certification, so as to trigger Teva's exclusivity period. The NDA holder granted Apotex covenants-not-to-sue as to the two patents for which Apotex sought a declaratory judgment.

The Federal Circuit agreed that the facts of *Caraco* and *Janssen* were substantially similar, but for one crucial difference: Apotex stipulated to the validity, infringement, and enforceability of the third listed patent. Thus, even if Apotex won the declaratory judgment it sought, it could not obtain FDA approval of its ANDA until the expiration of the patent to which it stipulated validity and enforceability. *See Janssen*, 540 F.3d at 1361. As the district court in *Dey* aptly stated, "[a]s a result of the stipulation, Apotex placed itself on equal footing with Teva with respect to the earliest date it could conceivably enter the market." *Dey*, 595 F. Supp. 2d at 362 (following *Caraco* and concluding that declaratory judgment jurisdiction existed because the

court found "nothing equivalent to Apotex's stipulation" in the facts before it). The injury suffered by Apotex in *Janssen* was not the injury identified in *Caraco*, as plaintiff in *Caraco* sought to trigger the first-filer's exclusivity period "*at a time when [the first-filer] could obtain FDA approval and then launch its product.*" *Janssen*, 540 F.3d at 1361 (emphasis in original). Apotex could not have been "blocked from entering the market by an invalid patent" because it stipulated to that patent's validity. *Id.* The Federal Circuit concluded that the only harm Apotex suffered was its inability to market its generic drug *during* Teva's exclusivity period, "a result envisioned by the Hatch-Waxman Act," and "not a cognizable Article III controversy." *Id.* While the Federal Circuit in *Janssen* reaffirmed the holding in *Caraco*, stating that *Caraco* was "supported by Supreme Court precedent," *id.* at 1363, the court nonetheless distinguished *Caraco* and concluded that Apotex's claim did not present a justiciable Article III controversy. *Id.* Here, Eisai argues for the same treatment of *Caraco* based on the unique facts of this case.

IV. *Caraco* is Distinguishable, and This Court Has No Jurisdiction over Teva's Declaratory Judgment Claims

While many of the facts in the instant matter are similar to those that compelled the Federal Circuit to find jurisdiction in *Caraco*, several crucial distinctions exist between the circumstances Caraco encountered and those that Teva faces here. First, the dormant Ranbaxy exclusivity period, which indefinitely delays FDA approval of the Gate ANDA, does not present the only barrier to market entry by Teva under either of its ANDAs. The inability to win approval of the Gate ANDA does not prevent Teva from marketing a form of generic donepezil, because the FDA previously approved Teva's first ANDA. Gate is merely an unincorporated

division of Teva, and appears to have no legal status independent of Teva. Indeed, Teva is the only named plaintiff in this matter, and brings this suit "through its Gate Pharmaceuticals division." (Am. Compl. at 1.) Teva filed the second ANDA in Gate's name, allegedly at the FDA's request, only to avoid confusion, but this separate filing does not change the fact that Teva and Gate are essentially equivalent. Teva goes to great lengths in its brief to obscure and downplay the relationship between Teva and Gate, but Teva simply cannot claim that its asserted FDA-approval-blocking injury as to the Gate ANDA has wholly excluded Teva from the market in the same manner as Caraco was "effectively prevent[ed] from entering the drug market." *Caraco*, 527 F.3d at 1296.

Any alleged FDA-approval-blocking injury suffered by Teva through Gate fails to present a substantial controversy of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Teva seeks to trigger Ranbaxy's exclusivity period so as to accelerate approval of the Gate ANDA, but overlooks the fact that Teva itself shares in that exclusivity period based on its first-filed Paragraph IV certification against the '841 patent. Thus, the FDA cannot approve the Gate ANDA until Teva's *own* exclusivity period expires, aside from any impact of Ranbaxy's shared exclusivity period. Teva cannot presently exhaust its exclusivity period, or invoke it by marketing generic donepezil and then waiving the exclusivity period to facilitate quicker approval of the Gate ANDA, because the preliminary injunction issued by Judge Ackerman precludes Teva from marketing *any* version of generic donepezil as covered by the '841 patent. The preliminary injunction specifically applies to Gate. The preliminary injunction therefore presents a barrier to Teva's market entry not found in *Caraco*, and one that deprives any hypothetical FDA-approval-blocking injury of the requisite

immediacy and reality to warrant declaratory judgment jurisdiction.

Moreover, the preliminary injunction places Teva and Ranbaxy on an "equal footing" with respect to the Gate ANDA. *Dey*, 595 F. Supp. 2d at 362. *Janssen* does not directly control because Teva itself has not stipulated to the enforceability of the '841 patent. Indeed, Teva opposed the entry of the preliminary injunction and continues to challenge the enforceability of the '841 patent in the *Eisai v. Teva* litigation. However, the distinction drawn in *Janssen* has persuasive force here because the circumstances in the instant matter place Teva and Ranbaxy in the same position with regard to the Gate ANDA as were Apotex and Teva in *Janssen*. Due to Ranbaxy's Paragraph III certification, the relationship between Teva and Gate, and the impact of the preliminary injunction against Teva and Gate in the '841 action, at this time both Teva (through Gate) and Ranbaxy cannot launch their generic versions of Aricept® until the expiration of the '841 patent. Thus, unlike the injury in *Caraco*, the harm to Teva from the delay in approval of the Gate ANDA does not result from the inability to trigger the Ranbaxy exclusivity period absent a court judgment on the DJ patents. Rather, as in *Janssen*, any delay occasioned here by Teva's inability to market the Gate version during Ranbaxy's exclusivity period, once that period is triggered, results from the operation of the Hatch-Waxman Act and its grant of an exclusivity period, not any act by Eisai.

Teva contends that because the Gate ANDA concerns a different product than the first ANDA, the approval of that first ANDA makes no difference here, and Teva requires a declaratory judgment to redress the independent harm it suffers due to the inability to trigger the Ranbaxy exclusivity period. However, the preliminary injunction explicitly applies to Teva and Gate, and at this time has the same effect on Teva as Ranbaxy's Paragraph III certification does

on Ranbaxy: Teva, through Gate, cannot market any form of generic donepezil, regardless of the impact of Ranbaxy's exclusivity period on eventual FDA approval of the Gate ANDA. Eisai and Teva are currently litigating the enforceability of the '841 patent, and *if* Teva ultimately prevails in that action, the preliminary injunction will be lifted. This Court expresses no opinion on the merits of the parties' arguments in the '841 patent action and the potential outcome of that case. However, because one may only speculate at this time as to whether the preliminary injunction will be lifted and whether Teva may market any form of generic donepezil prior to the expiration of the '841 patent, the potential injury alleged by Teva here lacks the sufficient immediacy and reality required to establish declaratory judgment jurisdiction. Teva must show that declaratory judgment jurisdiction existed at the time of filing and at all stages of review. *See, e.g.*, *Janssen*, 540 F.3d at 1360; *PharmaNet*, 2009 WL 396180, at *3. Even if this Court could possibly exercise jurisdiction in the future over Teva's claims for declaratory judgment, jurisdiction is wanting at this time.

Teva does not allege the same FDA-approval-blocking injury found sufficient for declaratory judgment jurisdiction in *Caraco*. This Court therefore will decline to extend *Caraco* to the different, unique facts of this case. Other courts, including a court in this District, have similarly declined to apply *Caraco* outside of the factual and legal context presented in that case. *See Dr. Reddy's Labs., Ltd. v. AstraZeneca AB*, No. 08-2496, 2008 WL 4056533, at *5-6 (D.N.J. Aug. 28, 2008) (finding *Caraco* inapplicable to amended version of Hatch-Waxman Act); *Ivax Pharms., Inc. v. AstraZeneca AB*, No. 08-2165, 2008 WL 4056518, at *4-5 (D.N.J. Aug. 28, 2008) (same). For the same reasons that the covenant-not-to-sue defeats declaratory judgment jurisdiction on the facts of this case with regard to the '911 and '760 patents, Eisai's statutory

disclaimers of the '864 and '321 patents prevent any substantial controversy regarding those patents. *See Merck*, 2007 WL 4082616, at *5 (finding, post-*MedImmune*, no declaratory judgment jurisdiction for claims regarding disclaimed patents); *see also Belk, Inc. v. Meyer Corp.*, No. 07-168, 2008 WL 2704792, at *3-4 (W.D.N.C. July 7, 2008) (same). This Court concludes that this case presents no justiciable Article III controversy, because under all the circumstances of this case, the facts do not "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127.

Even if the jurisdictional requirements of *MedImmune* were satisfied, this Court would exercise its broad discretion pursuant to the Declaratory Judgment Act to decline jurisdiction. *See MedImmune*, 549 U.S. at 136; *Wilton*, 515 U.S. at 286-87. For the same reasons stated above with regard to Article III jurisdiction, this Court concludes that declining jurisdiction would be consistent with the purposes of the Declaratory Judgment Act and properly conserve judicial resources. Furthermore, the particular circumstances of this case, including the multiple ANDAs and the relationship between Teva and Gate, persuade this Court that the exercise of jurisdiction is unwarranted.

Conclusion

For the foregoing reasons, this Court will grant Eisai's renewed motion to dismiss for lack of subject matter jurisdiction (Doc. No. 20). An appropriate form of order accompanies this memorandum opinion.

Dated: September 9, 2009
Newark, New Jersey

S/Garrett E. Brown, Jr.
Garrett E. Brown, Jr., Chief Judge
United States District Court